4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2023-N-1554]**

# Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Qualitative Feedback on Agency Service Delivery

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0697. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

## Qualitative Feedback on Agency Service Delivery

FDA will garner qualitative customer and stakeholder feedback using a variety of methods in order to gain useful insights into customer or stakeholder perceptions, experiences, and expectations; provide an early warning of issues with service; or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance.

Respondents to this collection of information cover a broad range of customers and stakeholders who have specific characteristics related to certain products or services regulated by FDA. These stakeholders include members of the general public, healthcare professionals, industry, and others who have experience with a product under FDA's jurisdiction.

In the *Federal Register* of May 25, 2023 (88 FR 33889), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but it was outside the scope of the PRA.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

| Activity | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|
| Focus groups | 3,000 | 1 | 3,000 | 1.75 | 5,250 |
| Customer comment cards/forms | 1,500 | 1 | 1,500 | 0.25 (15 minutes) | 375 |
| Small discussion groups | 800 | 1 | 800 | 1.75 | 1,400 |
| Customer satisfaction surveys | 20,000 | 1 | 20,000 | 0.33 (20 minutes) | 6,600 |
| Usability studies | 1,100 | 1 | 1,100 | 1 | 1,100 |

Table 1.--Estimated Annual Reporting Burden[1]

| Activity | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|
| Total | | | | | 14,725 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we increased the number of respondents for focus groups, customer comment cards/forms, customer satisfaction surveys, and usability studies. This adjustment results in an overall burden increase of 6,234 hours.

**Dated:** November 21, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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